

"Express Mail" Label No. EL 951611709US

Date of Deposit: February 25, 2002

PATENT  
Attorney Docket No.: 014058-008591US

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Assistant Commissioner for Patents  
Washington, D.C. 20231

By: \_\_\_\_\_

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Reed *et al.*

Application No.: Not yet assigned

Filed: Herewith

For: COMPOUNDS AND METHODS  
FOR IMMUNOTHERAPY AND  
DIAGNOSIS OF TUBERCULOSIS

Examiner: Not yet assigned

Art Unit: Not yet assigned

PRELIMINARY AMENDMENT

Box Patent Application  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Please amend the above-identified application as follows.

IN THE SPECIFICATION

On page 1, lines 6-17, please amend the application as follows:

This application is a continuation of U.S. Application No. 09/072,967, filed May 5, 1998, which is a continuation-in-part of U.S. Application No. 09/025,197, filed February 18, 1998, now abandoned; which is a continuation-in-part of U.S. Application No. 08/942,578, filed October 1, 1997, now abandoned; which is a continuation-in-part of U.S. Application No. 08/818,112, filed March 13, 1997, now U.S. Patent No. 6,290,969; which is a

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continuation-in-part of U.S. Application No. 08/730,510, filed October 11, 1996, now abandoned; which claims priority from PCT Application No. PCT/US 96/14674, filed August 30, 1996; and is a continuation-in-part of U.S. Application No. 08/680,574, filed July 12, 1996, now abandoned; which is a continuation-in-part of U.S. Application No. 08/659,683, filed June 5, 1996, now abandoned; which is a continuation-in-part of U.S. Application No. 08/620,874, filed March 22, 1996, now abandoned; which is a continuation-in-part of U.S. Application No. 08/533,634, filed September 22, 1995, now abandoned; which is a continuation-in-part of U.S. Application No. 08/523,436, filed September 1, 1995, now abandoned, each of which is herein incorporated by reference in their entirety.

#### IN THE CLAIMS

Please cancel claims 1-37 without prejudice to subsequent revival.

Please add new claims 38-51 as follows. Support for the new claims can be found in the claims as originally filed in parent patent application 09/072,967.

38. (new) An isolated nucleic acid encoding an immunogenic portion of a soluble *M. tuberculosis* antigen, wherein the nucleic acid hybridizes under moderately stringent conditions to a nucleotide sequence selected from the group consisting of SEQ ID NO:26-51, 138, 139, 163-183, 201, 240, 242-247, 253-256, 295-298, 309, 316, 318-320, 322, 324, 328, 329, 333, 335, 337, 339, and 341, or a complement thereof.

39. (new) An expression vector comprising a nucleic acid of claim 38.

40. (new) A host cell comprising an expression vector of claim 39.

41. (new) The host cell of claim 40, wherein the cell is selected from the group consisting of *E. coli*, yeast, and mammalian cells.

42. (new) A composition comprising a nucleic acid of claim 38 and a physiologically acceptable carrier.

43. (new) An isolated polypeptide encoded by a nucleic acid of claim 38.
44. A fusion protein comprising a polypeptide according to claim 43.
45. (new) A composition comprising a polypeptide of claim 43 or a fusion protein of claim 44 and a physiologically acceptable carrier.
46. (new) The composition of claim 45, further comprising a non-specific immune response enhancer.
47. (new) The composition of claim 46, wherein the non-specific immune response enhancer is an adjuvant.
48. (new) A method of inducing protective immunity in a patient, the method comprising the steps of administering to the subject a composition according to claim 45.
49. (new) A vaccine comprising a polypeptide of claim 43 or a fusion protein of claim 44; and a physiologically acceptable carrier.
50. (new) A method for detecting tuberculosis in a subject, said method comprising the steps of :
- (a) contacting dermal cells of a patient with a polypeptide of claim 43; and
  - (b) detecting an immune response on the patient's skin and therefrom detecting tuberculosis in the patient.
51. (new) A diagnostic kit comprising:
- (a) a polypeptide of claim 43; and

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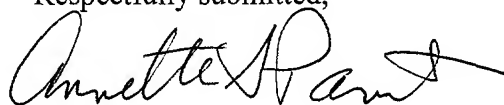
(b) apparatus sufficient to contact the polypeptide with the dermal cells of a patient.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Annette S. Parent  
Reg. No. 42,058

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APPENDIX A  
VERSION WITH MARKINGS TO SHOW CHANGE

IN THE SPECIFICATION

On page 1, lines 6-17, please amend the application as follows:

This application is a continuation of U.S. Application No. 09/072,967, filed May 5, 1998, which is a continuation-in-part of U.S. Application No. 09/025,197, filed February 18, 1998, now abandoned; which is a continuation-in-part of U.S. Application No. 08/942,578, filed October 1, 1997, now abandoned; which is a continuation-in-part of U.S. Application No. 08/818,112, filed March 13, 1997, now U.S. Patent No. 6,290,969; which is a continuation-in-part of U.S. Application No. 08/730,510, filed October 11, 1996, now abandoned; which claims priority from PCT Application No. PCT/US 96/14674, filed August 30, 1996; and is a continuation-in-part of U.S. Application No. 08/680,574, filed July 12, 1996, now abandoned; which is a continuation-in-part of U.S. Application No. 08/659,683, filed June 5, 1996, now abandoned; which is a continuation-in-part of U.S. Application No. 08/620,874, filed March 22, 1996, now abandoned; which is a continuation-in-part of U.S. Application No. 08/533,634, filed September 22, 1995, 1995, now abandoned; which is a continuation-in-part of U.S. Application No. 08/523,436, filed September 1, 1995, now abandoned, each of which is herein incorporated by reference in their entirety.

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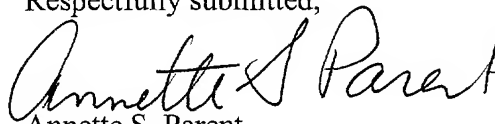
LETTER TO OFFICIAL DRAFTSPERSON

Box Patent Application  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Attached to be made of record in this application are nineteen (19) sheets of formal  
drawings, as submitted on August 23, 2001 in parent case Serial No. 09/072,967.

Respectfully submitted,

  
Annette S. Parent  
Reg. No. 42,058

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